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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,165	09/09/2003	Randal Lee Schapaugh	00550.US1	5705

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

MAIL DATE	DELIVERY MODE
08/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,165	SCHAPAUGH ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-25,27 and 32-35* is/are rejected.

7)☒ Claim(s) *4, 26, 28-31, 36-38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-38 are objected to because of the following informalities: On line 6 of claim 1, the phrase –so that the non-aqueous liquid composition contacts the aqueous dissolution medium-- should be inserted after the word "medium" so as to make it clear that the non-aqueous liquid composition actually comes into contact with the aqueous dissolution medium when the two are combined in part b) of claim 1. At the end of claims 21-22, the phrase –for transfer of the analyte—should be inserted after the word "pH" so as to make it clear what the pH is optimal for. Appropriate correction is required.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-3, 5-25, 27 and 32-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-11, 13-17, 19, 21-24, 27, 29-30 and 35 of copending Application No. 10/658,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method of characterizing the transfer of an analyte from a non-aqueous liquid composition to an aqueous medium comprising the steps of providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base, combining the non-aqueous liquid composition with an aqueous dissolution medium, agitating and mixing the non-aqueous liquid composition and the aqueous dissolution medium and determining the amount of analyte in the aqueous dissolution medium at multiple time points after the combining and agitating steps. The claims of U.S. application serial no. 10/658,164 fail to recite that an emulsion forms upon agitating and mixing the non-aqueous liquid composition and the aqueous dissolution medium. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to realize that an emulsion inherently forms as a result of the contact and agitation between the aqueous dissolution medium and the non-aqueous liquid composition recited in the claims of U.S. application serial no. 10/658,164 since the method recited in the claims of application serial no. 10/658,164 combines an oil such as cottonseed oil as a non-aqueous liquid base with an analyte such as ceftiofur, which are the same types of non-aqueous base and analyte as recited in the instant claims, and then combines this non-aqueous liquid composition with an

aqueous dissolution medium, which is also the same step as recited in the instant claims. Therefore, one of ordinary skill in the art would expect that an emulsion would form between the non-aqueous liquid composition and the aqueous dissolution medium in the method recited in the claims of U.S. application serial no. 10/658,164 since the same type of reagents are being combined under the same conditions (i.e. agitation) as in the claims of the instant invention, and an emulsion inherently forms between two different dispersed phases (i.e. an oil and an aqueous liquid) when the phases are immiscible liquids.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Applicant's arguments filed May 30, 2007 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on March 6, 2007 have been withdrawn in view of Applicants' amendments to the claims. However, the claims are objected to above so as to provide further clarification to claims 1, 21 and 22. The previous rejection of the claims under 35 USC 102(b) as being anticipated by Dunn et al, and the previous rejection of the claims under 35 USC 103 as being obvious over Dunn et al in view of Conti et al have been withdrawn in view of Applicants' persuasive arguments.

Applicants argue the provisional rejection of the claims for nonstatutory obviousness-type double patenting as being unpatentable over claims in application serial no. 10/658,164 by stating that the formation of an emulsion when oil and water mixtures are agitated is not inherent since when such mixtures are stirred by a paddle assembly, the non-aqueous oil generally floats

on the surface of the aqueous water. Applicants argue that in application serial no. 10/658,164, the specification and figures describe a paddle assembly for forming an even layer of the non-aqueous composition on the surface of the aqueous dissolution medium, and such is not an emulsion as recited in the instant claims since an emulsion requires the dispersed phase to be broken up into small droplets, which are dispersed in the continuous phase. Therefore, Applicants argue that application serial no. 10/658,164 fails to recite the formation of an emulsion, and because of this, teaches away from the instant invention. In response to these arguments, it is noted that a rejection made under the doctrine of obviousness-type double patenting is based upon what the claims in an application recite, not what the specification or figures disclose. Each of the independent claims in both the instant application and in application serial no. 10/658,164 do not recite an oil and water mixture, but rather recite the broad combination of a non-aqueous liquid composition and an aqueous dissolution medium, which could under special circumstances form an emulsion when stirred by a paddle assembly, as admitted by Applicants on page 14 of the instant specification. In addition, instant claim 1 only recites a step of "agitating" the non-aqueous liquid composition and the aqueous liquid, but does not specify how this agitating is performed. Since Applicants admit that an emulsion may form between a non-aqueous liquid composition and an aqueous liquid under special circumstances using stirring with a paddle assembly, and instant claim 1 does not specify how the "agitating" is performed, the emulsion recited in claim 1 could result from stirring with a paddle assembly as taught by application serial no. 10/658,164 under special circumstances. In addition, the broad independent claims 1 and 35 in application serial no. 10/658,164 do not recite a paddle assembly for stirring the non-aqueous liquid composition and the aqueous liquid, but

rather recite a "dissolution testing apparatus", which is broad enough to encompass a shaker that agitates the non-aqueous liquid composition and the aqueous liquid into an emulsion. For these reasons, Applicants' arguments regarding the obviousness-type double patenting rejection are not persuasive, and this rejection has been maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 8, 2007

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP [redacted] 1700